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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,864	03/08/2001	Archie Woodworth	SFP 5772 (1417Y P552)	6736

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EXAMINER
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HUYNH, LOUIS K

ART UNIT	PAPER NUMBER
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3721

DATE MAILED: 08/07/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

# Office Action Summary

Application No.

09/801,864

Applicant(s)

WOODWORTH ET AL.

Examiner

Louis K. Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 28*  
I. Claims ~~1-17~~, drawn to a hollow container, classified in class 428, subclass 35.7.
- II. Claims 29-35, drawn to a method for filling and sterilizing a syringe, classified in class 53, subclass 426.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case (1) the process as claimed can be used to make other and materially different product such as a sterilized container containing sterile water; and (2) the product as claimed can be made by another and materially different process such as one having step sterilizing the elastomeric component.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mr. Joseph Fuchs on July 31, 2003 a provisional election was made without traverse to prosecute the invention of Group II, claims 29-35.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-28 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 & 35, lines 11-12: "the sterile water for injection syringe meets the requirements of the United States Pharmacopeia for sterile water for injection" is indefinite because it is unclear as to what requirements applicants are referring to; therefore, the metes and bounds and/or scope of the claims can not be established.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Heffernan et al. (US 5,620,425).

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Heffernan discloses a method for filling a syringe including the steps of: providing a syringe body (1) of a suitable plastic (column 4, lines 42-47) and having an opening (at end 4); sterilizing the syringe body (column 6, lines 16-20); transfer the sterilized syringe body to a class 100 sterile environment (column 7, lines 34-36); immediately filling the sterilized syringe body with an appropriate quantity of sterile water for injection (column 7, lines 6-8); sealing the opening of the sterilized syringe body with an elastomeric component of a halobutyl-based elastomer (column 5, lines 8-10 & column 6, lines 22-23); and the filled and sealed syringe produced by the method of Heffernan is expected to meet the United States Pharmacopoeia in order to be sold and used in the United States of America.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heffernan (US 5,620,425) in view of AAPA (Applicant Admitted Prior Art).

The method of Heffernan meets all of applicant's claimed subject matter but lacks the specific teaching of the norbornene and ethylene copolymer has a heat deflection temperature at 0.45 Mpa from about 70°C to about 200°C, or from about 75°C to about 150°C, or from about 76°C to about 149°C.

However, AAPA discloses that norbornene and ethylene copolymers are well known and sold under trade names such as TOPAZ, ZEONEX, ZEONOR, CZ resin, APEL, etc. (page 6,

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lines 10-26), and the properties including heat deflection of these material can be modified to a preferred range is well within the knowledge of a skilled person in the art.

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified the method of Heffernan by having provided the syringe body of a suitable plastic having the specific heat deflection ranges as claimed, as taught by AAPA, in order for the syringe body to be exposed at a high temperature without being deformed in shape.

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heffernan (US 5,620,425) in view of AAPA (Applicant Admitted Prior Art) as applied to claim 32 above; and further in view of Bayan et al. (US 4,978,714).

The modified method of Heffernan meets all of applicant's claimed subject matter but lacks the specific teaching of the halobutyl-based elastomer is a chlorobutyl-based elastomer.

However, Bayan teaches that chlorobutyl-based elastomer is a form halobutyl-based elastomer (column 5, lines 15-24) and the halobutyl-based elastomer is suitable for pharmaceutical products such as vial stopper, syringe tips and the like (column 7, lines 23-30).

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have further modified the method of Heffernan by having formed the elastomeric component from chlorobutyl-based elastomer, as taught by Bayan, since chlorobutyl-based elastomer is a form of halobutyl-based elastomer.

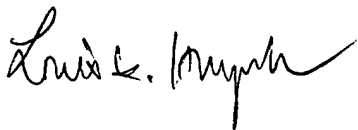
*Conclusion*

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure has been cited on form PTO-892 along with the applied prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (703) 306-5694. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (703) 308-2187. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



Louis K. Huynh  
Patent Examiner  
Art Unit 3721

LH  
August 1, 2003